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Wockhardt Limited and Wockhardt USA LLC*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL) Civil Action No.: 13-cv-06427-JAP-TJB
COMPANY LIMITED, TAKEDA) Honorable Joel A. Pisano, U.S.D.J.
PHARMACEUTICALS U.S.A., INC., and) Honorable Tonianne J. Bongiovanni, U.S.M.J.
TAKEDA PHARMACEUTICALS)
AMERICA, INC.,) **(ELECTRONICALLY FILED)**
Plaintiffs,)
v.)
WOCKHARDT BIO AG, WOCKHARDT)
LIMITED and WOCKHARDT USA LLC,)
Defendants.)
)

**WOCKHARDT BIO AG, WOCKHARDT LIMITED AND WOCKHARDT USA LLC'S
ANSWER TO THE AMENDED COMPLAINT AND AMENDED COUNTERCLAIMS**

Defendants Wockhardt Bio AG, Wockhardt Limited and Wockhardt USA LLC (collectively, “Wockhardt”) hereby answer the Amended Complaint of Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc., (collectively, “Takeda”) as follows:

THE PARTIES¹

1. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 1 of the Amended Complaint, and therefore denies those allegations.

2. Wockhardt admits that according to the United State Patent and Trademark Office (“PTO”) assignment database U.S. Patent Nos. 6,328,994 (“the ’994 patent”), 7,431,942 (“the ’942 patent”), and 7,875,292 (“the ’292 patent”) are assigned to Takeda Pharmaceutical Company Limited. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 2 of the Amended Complaint, and therefore denies those allegations.

3. Wockhardt admits that according to the FDA website, Takeda Pharms USA is the registered holder of New Drug Application No. 21-428. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 3 of the Amended Complaint, and therefore denies those allegations.

4. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 4 of the Amended Complaint, and therefore denies those allegations.

¹ For the Court’s convenience, Wockhardt has incorporated the “Headings” that appear in the Amended Complaint. Wockhardt, however, does not necessarily agree with the characterizations of such Headings, and does not waive any right to object to those characterizations.

5. Wockhardt admits that Wockhardt Bio AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Baarestrasse 43, 6300 Zug, Switzerland. Wockhardt further admits Wockhardt USA LLC is a subsidiary of Wockhardt Bio AG. Wockhardt admits that Wockhardt USA LLC sells or distributes generic pharmaceutical products throughout the United States, including this District. For purposes of this action only, Wockhardt does not contest jurisdiction in this Court. Except as expressly admitted, Wockhardt denies the remaining allegations of Paragraph 5 of the Amended Complaint.

6. Wockhardt admits that Wockhardt Limited is a company organized and existing under the laws of India, having a principal place of business at Bandra-Kurla Complex, Bandra East, Mumbai 400 051, Maharashtra, India. Wockhardt further admits that Wockhardt Bio AG and Wockhardt USA LLC are subsidiaries of Wockhardt Limited. Wockhardt admits that Wockhardt USA LLC sells or distributes generic pharmaceutical products throughout the United States, including this District. Except as expressly admitted, Wockhardt denies the remaining allegations of Paragraph 6 of the Amended Complaint.

7. Wockhardt admits that Wockhardt USA LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, New Jersey, 07054. Wockhardt admits that Wockhardt USA LLC is a subsidiary of Wockhardt Limited and Wockhardt Bio AG. Wockhardt further admits that Wockhardt USA, Wockhardt Limited and Wockhardt Bio AG together develop, manufacture, market import, offer to sell and sell generic drug products throughout the United States, including this District. Wockhardt denies the remaining allegations of Paragraph 7 of the Amended Complaint.

8. Paragraph 8 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 8 of the Amended Complaint.

JURISDICTION AND VENUE

9. Wockhardt admits that the Amended Complaint purports to be an action arising under the patent laws of the United States of America, Title 35, United States Code and that the court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Except as expressly admitted, Wockhardt denies the allegations of Paragraph 9 of the Amended Complaint.

10. Paragraph 10 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, and for the purposes of this action only, Wockhardt Bio AG does not contest personal jurisdiction in this Court. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 10 of the Amended Complaint.

11. Paragraph 11 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that in *Novartis Pharmaceuticals Corp. et al. v. Wockhardt USA LLC et al.*, 2:12-CV-3967-SDW-MCA (D.N.J.), Wockhardt Limited did not contest personal jurisdiction for purposes of that action only. For purposes of this action only, Wockhardt Limited does not contest personal jurisdiction in this Court. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 11 of the Amended Complaint.

12. Paragraph 12 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, and for purposes of this action only, Wockhardt USA LLC does not contest personal jurisdiction in this Court. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 12 of the Amended Complaint.

13. Paragraph 13 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that in *Novartis Pharmaceuticals Corp. et al. v. Wockhardt USA LLC et al.*, 2:12-CV-3967-SDW-MCA (D.N.J.), Wockhardt USA LLC did not contest personal jurisdiction for purposes of that action only. For purposes of this action only, Wockhardt USA LLC does not contest personal jurisdiction in this Court. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 13 of the Amended Complaint.

14. Paragraph 14 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent a response is required, and for purposes of this action only, Wockhardt admits that venue is proper.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

15. Wockhardt admits that the '994 patent, on its face, is entitled "Orally Disintegrating Tablets," and states the date of issue as December 11, 2001. Wockhardt further admits that the '994 patent, on its face, lists Takeda Chemical Industries, Ltd. as the assignee and names Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata as inventors. Wockhardt further admits that Exhibit A to the Amended Complaint purports to be a copy of the '994 patent. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 15 of the Amended Complaint, and therefore denies those allegations.

16. Wockhardt admits that the '942 patent, on its face, is entitled "Orally Disintegrable Tablets," and states the date of issue as October 7, 2008. Wockhardt further admits that the '942 patent, on its face, lists Takeda Pharmaceutical Company Limited as the assignee and names Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata as inventors. Wockhardt further admits that Exhibit B to the Amended Complaint purports to be a copy of the '942

patent. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 16 of the Amended Complaint, and therefore denies those allegations.

17. Wockhardt admits that the '292 patent, on its face is entitled "Orally Disintegrable Tablets," and states the date of issue as January 25, 2011. Wockhardt further admits that the '292 patent, on its face, lists Takeda Pharmaceutical Company Limited as the assignee and Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata as inventors. Wockhardt further admits that Exhibit C to the Amended Complaint purports to be a copy of the '292 patent. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 17 of the Amended Complaint, and therefore denies those allegations.

18. Wockhardt admits that the FDA website lists August 30, 2002 as the approval date for NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg and Takeda Pharms USA as the holder of NDA No. 21-428. Wockhardt is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 18 of the Amended Complaint, and therefore denies those allegations except as expressly admitted.

19. Wockhardt admits the allegations of Paragraph 19 of the Amended Complaint.

20. Wockhardt admits that it is in the business of commercial manufacture, use, offer to sell, or sale of generic pharmaceutical products worldwide. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 20 of the Amended Complaint.

21. Wockhardt admits that it is in the business of commercial manufacture, use, offer to sell, or sale of generic pharmaceutical products in the United States. For purposes of this

action only, Wockhardt does not contest personal jurisdiction in this Court. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 21 of the Amended Complaint.

22. Wockhardt admits that it is in the business of commercial manufacture, use, offer to sell, or sale of generic pharmaceutical products in the United States. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 22 of the Amended Complaint.

23. Wockhardt admits that Wockhardt Bio AG filed an Abbreviated New Drug Application (“ANDA”) No. 205560, seeking approval to market a generic version of lansoprazole delayed release orally disintegrating tablets and that the proprietary name of the drug as listed in the Orange Book is Prevacid®. Wockhardt further admits that prior to filing ANDA No. 205560, Wockhardt Bio AG reviewed the patents-in-suit. Wockhardt denies the remaining allegations of Paragraph 23 of the Amended Complaint.

24. Paragraph 24 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 24 of the Amended Complaint.

25. Admitted.

26. Wockhardt admits that Wockhardt USA LLC and Wockhardt Limited sent a letter to Plaintiffs dated September 17, 2013 notifying Plaintiffs that ANDA No. 205560 includes a Paragraph IV Certification. Wockhardt further admits that the notification expressed Wockhardt Bio AG’s opinion that to the best of its knowledge, no valid, enforceable claim of the patents-in-suit will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 205560 has been submitted. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 26 of the Amended Complaint.

27. Paragraph 27 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 27 of the Amended Complaint.

28. Admitted.

29. Admitted.

30. Paragraph 30 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that Wockhardt Bio AG intends to seek approval of ANDA No. 205560 in order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale or sale of generic versions of lansoprazole delayed release orally disintegrating tablets. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 30 of the Amended Complaint.

FIRST CLAIM FOR RELIEF

(Direct Infringement of the '994 Patent by Defendants)

31. Wockhardt incorporates by reference each of its answers to Paragraphs 1 through 30 as though fully set forth herein.

32. Wockhardt denies the allegations of Paragraph 32 of the Amended Complaint.

33. Wockhardt denies the allegations of Paragraph 33 of the Amended Complaint.

34. Wockhardt admits that it was aware of the existence of the '994 patent prior to the filing of ANDA No. 205560. Wockhardt denies the remaining allegations of Paragraph 34 of the Amended Complaint.

35. Wockhardt denies the allegations of Paragraph 35 of the Amended Complaint.

36. Wockhardt denies the allegations of Paragraph 36 of the Amended Complaint.

37. Wockhardt denies the allegations of Paragraph 37 of the Amended Complaint.

SECOND CLAIM FOR RELIEF

(Inducement of Infringement of the '994 Patent by Wockhardt Bio AG and Wockhardt Limited)

38. Wockhardt incorporates by reference each of its answers to Paragraphs 1 through 37 as though fully set forth herein.

39. Paragraph 39 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 39 of the Amended Complaint.

40. Paragraph 40 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that Wockhardt USA LLC was involved in the preparation and filing of ANDA No. 205560 with the FDA. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 40 of the Amended Complaint.

41. Wockhardt denies the allegations of Paragraph 41 of the Amended Complaint.

42. Wockhardt denies the allegations of Paragraph 42 of the Amended Complaint.

43. Paragraph 43 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 43 of the Amended Complaint.

44. Wockhardt denies the allegations of Paragraph 44 of the Amended Complaint.

45. Wockhardt denies the allegations of Paragraph 45 of the Amended Complaint.

46. Wockhardt denies the allegations of Paragraph 46 of the Amended Complaint.

47. Paragraph 47 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 47 of the Amended Complaint.

48. Wockhardt denies the allegations of Paragraph 48 of the Amended Complaint.

THIRD CLAIM FOR RELIEF

(Direct Infringement of the '942 Patent by Defendants)

49. Wockhardt incorporates by reference each of its answers to Paragraphs 1 through 48 as though fully set forth herein.

50. Wockhardt denies the allegations of Paragraph 50 of the Amended Complaint.

51. Wockhardt denies the allegations of Paragraph 51 of the Amended Complaint.

52. Wockhardt admits that it was aware of the existence of the '942 patent prior to the filing of ANDA No. 205560. Wockhardt denies the remaining allegations of Paragraph 52 of the Amended Complaint.

53. Wockhardt denies the allegations of Paragraph 53 of the Amended Complaint.

54. Wockhardt denies the allegations of Paragraph 54 of the Amended Complaint.

55. Wockhardt denies the allegations of Paragraph 55 of the Amended Complaint.

FOURTH CLAIM FOR RELIEF

(Inducement of Infringement of the '942 Patent by Wockhardt AG and Wockhardt Limited)

56. Wockhardt incorporates by reference each of its answers to Paragraphs 1 through 55 as though fully set forth herein.

57. Paragraph 57 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 57 of the Amended Complaint.

58. Paragraph 58 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that Wockhardt USA LLC was involved in the preparation and filing of ANDA No. 205560 with the FDA. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 58 of the Amended Complaint.

59. Wockhardt denies the allegations of Paragraph 59 of the Amended Complaint.

60. Wockhardt denies the allegations of Paragraph 60 of the Amended Complaint.

61. Paragraph 61 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 61 of the Amended Complaint.

62. Wockhardt denies the allegations of Paragraph 62 of the Amended Complaint.

63. Wockhardt denies the allegations of Paragraph 63 of the Amended Complaint.

64. Wockhardt denies the allegations of Paragraph 64 of the Amended Complaint.

65. Paragraph 65 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 65 of the Amended Complaint.

66. Wockhardt denies the allegations of Paragraph 66 of the Amended Complaint.

FIFTH CLAIM FOR RELIEF

(Direct Infringement of the '292 Patent by Defendants)

67. Wockhardt incorporates by reference each of its answers to Paragraphs 1 through 66 as though fully set forth herein.

68. Wockhardt denies the allegations of Paragraph 68 of the Amended Complaint.

69. Wockhardt denies the allegations of Paragraph 69 of the Amended Complaint.

70. Wockhardt admits that it was aware of the existence of the '292 patent prior to the filing of ANDA No. 205560. Wockhardt denies the remaining allegations of Paragraph 70 of the Amended Complaint.

71. Wockhardt denies the allegations of Paragraph 71 of the Amended Complaint.

72. Wockhardt denies the allegations of Paragraph 72 of the Amended Complaint.

73. Wockhardt denies the allegations of Paragraph 73 of the Amended Complaint.

SIXTH CLAIM FOR RELIEF

(Inducement of Infringement of the '292 Patent by Wockhardt AG and Wockhardt Limited)

74. Wockhardt incorporates by reference each of its answers to Paragraphs 1 through 73 as though fully set forth herein.

75. Paragraph 75 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 75 of the Amended Complaint.

76. Paragraph 76 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that Wockhardt USA LLC was involved in the preparation and filing of ANDA No. 205560 with the FDA. Except as expressly admitted, Wockhardt denies the allegations of Paragraph 76 of the Amended Complaint.

77. Wockhardt denies the allegations of Paragraph 77 of the Amended Complaint.

78. Wockhardt denies the allegations of Paragraph 78 of the Amended Complaint.

79. Paragraph 79 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 79 of the Amended Complaint.

80. Wockhardt denies the allegations of Paragraph 80 of the Amended Complaint.

81. Wockhardt denies the allegations of Paragraph 81 of the Amended Complaint.

82. Wockhardt denies the allegations of Paragraph 82 of the Amended Complaint.

83. Paragraph 83 of the Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 83 of the Amended Complaint.

84. Wockhardt denies the allegations of Paragraph 84 of the Amended Complaint.

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF

Wockhardt denies that Plaintiffs are entitled to the relief they seek in Paragraphs A-F or any relief at all for the allegations made in the Amended Complaint.

AFFIRMATIVE DEFENSES

On information and belief, Wockhardt asserts the following Affirmative Defenses to Plaintiffs' Amended Complaint:

FIRST AFFIRMATIVE DEFENSE

(Non-infringement of U.S. Patent No. 6,328,994, U.S. Patent No. 7,431,942 and U.S. Patent No. 7,875,292)

85. The manufacture, use, sale, offer for sale and/or importation into the United States of the product covered by Wockhardt's ANDA No. 205560 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the U.S. Patent Nos. 6,328,994 ("the '994 patent"), 7,431,942 ("the '942 patent"), and 7,875,292 ("the '292 patent").

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

86. The claims of the '994 patent, '942 patent, and the '292 patent are invalid for failing to satisfy one or more of the requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

Wockhardt reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability, as well as any defense(s) raised by another defendant in this action.

WOCKHARDT'S AMENDED COUNTERCLAIMS

Defendants/Counterclaimants, Wockhardt Bio AG ("Wockhardt AG") Wockhardt Limited ("Wockhardt Limited") and Wockhardt USA LLC ("Wockhardt USA") (collectively, "Wockhardt"), by and through their undersigned attorneys, assert the following Amended Counterclaims against Plaintiffs/Counterdefendants, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Counterdefendants" and/or "Takeda") for declaratory judgment that U.S. Patent Nos. 6,328,994 ("the '994 patent"), 7,431,942 ("the '942 patent") and 7,875,292 ("the '292 patent") are invalid for violation of one or more of the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or are unenforceable or invalid under any judicially-created bases; and for declaratory judgment that no valid and enforceable claim of the '994, '942 and '292 patents are infringed by the Lansoprazole Delayed Release Orally Disintegrating Tablets described in Wockhardt's ANDA No. 205560 ("Wockhardt's ANDA Products").

PARTIES

1. Counterclaimant Wockhardt Bio AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland.

2. Counterclaimant Wockhardt Limited is a company organized and existing under the laws of India, having a principal place of business at Bandra-Kurla Complex, Bandra East, Mumbai 400 051, Maharashtra, India.

3. Counterclaimant Wockhardt USA is a limited liability company organized and existing under the laws of the State of Delaware and has a place of business at 20 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054.

4. On information and belief, and based on Counterdefendants' allegations, Counterdefendant Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

5. On information and belief, and based on Counterdefendants' allegations, Counterdefendant Takeda Pharmaceuticals U.S.A., Inc. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

6. On information and belief, and based on Counterdefendants' allegations, Takeda Pharmaceuticals America, Inc. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

7. On information and belief, and based on Counterdefendants' allegations, Counterdefendant Takeda Pharmaceutical Company Limited is the owner of record and assignee of the '994, '942 and the '292 patents.

NATURE OF THE ACTION

8. Wockhardt seeks declaratory judgment that the '994, '942 and the '292 patents are invalid for violation of one or more of the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or are unenforceable or invalid under any judicially-created bases.

9. Wockhardt seeks declaratory judgment that no valid and enforceable claim of the '994, '942 and the '292 patents is infringed by Lansoprazole Delayed Release Orally Disintegrating Tablet product described in Wockhardt's ANDA No. 205560.

JURISDICTION AND VENUE

10. These amended counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction over these amended counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2201(b), 2202 and 35 U.S.C. § 271 (a), (b), (c) or (e)(2) based on an actual controversy between Wockhardt and Counterdefendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

12. This Court has personal jurisdiction over Counterdefendants based, *inter alia*, on the filing by Counterdefendants of this lawsuit in this jurisdiction.

13. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendants' choice of forum.

14. This is an action based upon an actual controversy between the parties concerning the invalidity and/or noninfringement of the '994, '942 and the '292 patents and Wockhardt's right to continue to seek approval of ANDA No. 205560 for Wockhardt's ANDA Products, and upon approval by the FDA, to manufacture, import, use, market, sell, and offer to sell Wockhardt's ANDA Products in the United States.

15. Wockhardt has been and presently is engaged in the submission of documents for FDA approval to engage in the commercial manufacture, importation, use, or sale of Wockhardt's ANDA Products that are the subject of Wockhardt's ANDA No. 205560, which Counterdefendants have alleged will infringe, or will induce infringement of, one or more claims of the '994, '942 and the '292 patents.

16. Counterdefendants have filed in this Court an infringement action to enforce the '994, '942 and the '292 patents.

17. Wockhardt has denied that the manufacture, use, sale, offer for sale and/or importation into the United States of the product covered by Wockhardt's ANDA No. 205560 directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '994, '942 and the '292 patents.

18. Wockhardt has further asserted that the '994 patent, '942 patent and the '292 patent are invalid for failing to satisfy one or more of the requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

19. In view of the foregoing, a conflict of asserted rights has arisen between Wockhardt and Counterdefendants with respect to the noninfringement and invalidity of the relevant claims of the '994, '942 and the '292 patents, and as to Wockhardt's right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Wockhardt's ANDA Products. An actual controversy therefore exists between Counterdefendants and Wockhardt.

COUNT I – DECLARATION OF NON-INFRINGEMENT OF THE '994 PATENT

20. Wockhardt realleges Paragraphs 1-19 of its Amended Counterclaims as though fully set forth herein.

21. Wockhardt incorporates Paragraphs 85 and 86 of its Affirmative Defenses as if fully set forth herein.

22. The manufacture, use, sale, offer for sale and/or importation into the United States of Wockhardt's ANDA Products does not and will not directly infringe, indirectly infringe,

induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '994 patent.

23. Wockhardt is entitled to judicial declaration that the '994 patent is not infringed.

COUNT II – DECLARATION OF INVALIDITY OF THE '994 PATENT

24. Wockhardt realleges Paragraphs 1-23 of its Amended Counterclaims as though fully set forth herein.

25. Wockhardt incorporates Paragraphs 85 and 86 of its Affirmative Defenses as if fully set forth herein.

26. The claims of the '994 patent are invalid for failing to satisfy one or more of the requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

27. Wockhardt is entitled to judicial declaration that the '994 patent is invalid.

COUNT III – DECLARATION OF NON-INFRINGEMENT OF THE '942 PATENT

28. Wockhardt realleges Paragraphs 1-27 of its Amended Counterclaims as though fully set forth herein.

29. Wockhardt incorporates Paragraphs 85 and 86 of its Affirmative Defenses as if fully set forth herein.

30. The manufacture, use, sale, offer for sale and/or importation into the United States of Wockhardt's ANDA Products does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '942 patent.

31. Wockhardt is entitled to judicial declaration that the '942 patent is not infringed.

COUNT IV – DECLARATION OF INVALIDITY OF THE '942 PATENT

32. Wockhardt realleges Paragraphs 1-31 of its Amended Counterclaims as though fully set forth herein.

33. Wockhardt incorporates Paragraphs 85 and 86 of its Affirmative Defenses as if fully set forth herein.

34. The claims of the '942 patent are invalid for failing to satisfy one or more of the requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

35. Wockhardt is entitled to judicial declaration that the '942 patent is invalid.

COUNT V – DECLARATION OF NON-INFRINGEMENT OF THE '292 PATENT

36. Wockhardt realleges Paragraphs 1-35 of its Amended Counterclaims as though fully set forth herein.

37. Wockhardt incorporates Paragraphs 85 and 86 of its Affirmative Defenses as if fully set forth herein.

38. The manufacture, use, sale, offer for sale and/or importation into the United States of Wockhardt's ANDA Products does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '292 patent.

39. Wockhardt is entitled to judicial declaration that the '292 patent is not infringed.

COUNT VI – DECLARATION OF INVALIDITY OF THE '292 PATENT

40. Wockhardt realleges Paragraphs 1-39 of its Amended Counterclaims as though fully set forth herein.

41. Wockhardt incorporates Paragraphs 85 and 86 of its Affirmative Defenses as if fully set forth herein.

42. The claims of the '292 patent are invalid for failing to satisfy one or more of the requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

43. Wockhardt is entitled to judicial declaration that the '292 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Wockhardt prays for the following relief:

- A. Dismissing the Amended Complaint with prejudice and denying each request for relief made by Plaintiffs;
- B. Declaring all of the claims of the '994, '942 and the '292 patents invalid and unenforceable;
- C. Declaring that no valid and enforceable claims of the '994, '942 or the '292 patents are infringed by the making, use, sale, offer for sale, marketing or importation into the United States of Wockhardt's ANDA Products.
- D. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Wockhardt its attorneys' fees, costs, and expenses in this action; and
- E. Awarding Wockhardt such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: May 9, 2014

By: s/ Karen A. Confoy
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CERTIFICATION PURSUANT TO L.CIV.R. 11.2

I hereby certify that the patents-in-suit have been asserted in the following pending actions: *Takeda Pharm. Co. Ltd. et al. v. Lupin Ltd. et al.*, Civ. Action No. 3:12-07333 (JAP) (TJB) (D.N.J.) (U.S. Patent No. 6,328,994) as stated in Plaintiffs' Amended Complaint, and *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharm. et al.*, Civ. Action No. 3:10-01723 (JAP) (TJB) (D.N.J.) currently on appeal to the Federal Circuit, Appeal No. 13-1406 (U.S. Patent No. 6,328,994).

Dated: May 9, 2014

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CERTIFICATE OF CM/ECF SERVICE

I certify that I caused electronic copies of the within **WOCKHARDT BIO AG, WOCKHARDT LIMITED, AND WOCKHARDT USA LLC'S ANSWER TO THE AMENDED COMPLAINT AND AMENDED COUNTERCLAIMS** to be electronically filed in accordance with the electronic case filing policies and procedures. I also certify that on this date, a copy was served via CM/ECF on counsel of record and by email on all counsel:

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